

10/566853

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US2005/047039

International filing date: 23 December 2005 (23.12.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/638,597
Filing date: 23 December 2004 (23.12.2004)

Date of receipt at the International Bureau: 24 February 2006 (24.02.2006)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland
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APPLICATION NUMBER: 60/638,597

FILING DATE: *December 23, 2004*

RELATED PCT APPLICATION NUMBER: *PCT/US05/47039*

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS *US60/638,597*



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PROVISIONAL APPLICATION FOR PATENT COVER SHEET
This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. ED 442035545 US

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Additional inventors are being named on the <u>N/A</u> separately numbered sheets attached hereto		
TITLE OF THE INVENTION (500 characters max):		
CLEANER FOR TUBULAR STRUCTURE		
Direct all correspondence to: CORRESPONDENCE ADDRESS		
<input checked="" type="checkbox"/> The address corresponding to Customer Number: 23676		
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ENCLOSED APPLICATION PARTS (check all that apply)		
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76		
<input type="checkbox"/> CD(s), Number of CDs _____		
<input checked="" type="checkbox"/> Specification Number of Pages <u>7</u>		
<input checked="" type="checkbox"/> Other (specify) <u>Return Receipt Postcard</u>		
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets <u>3</u>		
Application Size Fee: If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).		
METHOD OF PAYMENT OF FILING FEES AND APPLICATION SIZE FEE FOR THIS PROVISIONAL APPLICATION FOR PATENT		
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.		TOTAL FEE AMOUNT (\$)
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Date December 23, 2004

REGISTRATION NO. 38,134
(if appropriate)

Docket Number: 15731

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)			Docket No. 15731
Application Serial No. To be assigned	Filing Date December 23, 2004	Examiner N/A	Group Art Unit N/A
Inventor/Applicant(s): DEUTSCH, Harvey L.			
Invention: CLEANER FOR TUBULAR STRUCTURE			
<p>I hereby certify that the following correspondence:</p> <ol style="list-style-type: none">1. Provisional Application for Patent Cover Sheet (1 page)2. United States Provisional Patent Application (7 pages)3. 3 Sheets of Drawings (Figures 1-8)4. Return Receipt Postcard <p>is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 in an envelope addressed to: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:</p> <div style="border: 1px solid black; padding: 2px; display: inline-block;">December 23, 2004</div> <p style="text-align: center;">(Date)</p> <div style="text-align: right; margin-top: 20px;"><div style="border-top: 1px solid black; width: 100px; margin: 0 auto;"></div><div style="text-align: center;">Marilyn Paik (Typed or Printed Name of Person Mailing Paper or Fee)</div><div style="border-top: 1px solid black; width: 100px; margin: 0 auto;"></div><div style="text-align: center;">(Signature of Person Mailing Correspondence)</div><div style="border: 1px dashed black; border-radius: 15px; padding: 10px; margin: 10px auto; width: 150px; text-align: center;">ED442035545US</div><div style="text-align: center;">("Express Mail" Mailing Label No. ED 442035545 US)</div></div>			

CLEANER FOR TUBULAR STRUCTURE

BACKGROUND

There are a large variety of tubular structures having a central axial lumen used in medical applications, and in non-medical commercial and industrial applications. Examples of tubular structures used in medical applications include catheters, drains and tubes. In many such applications, the tubular structures are prone to collecting debris within the lumen causing a decrease or cessation of function, and necessitating that the tubular structure be cleaned or replaced.

In medical applications in particular, replacing tubular structures can be very costly, and can put a patient at increased risk of infection. Therefore, it is often preferable to clean the tubular structure. In some applications, the tubular structure can be cleaned by flushing the tubular structure with a liquid, thereby moving the debris distally. In many applications, however, flushing the debris distally is not acceptable.

Therefore, there is a need for a method of cleaning debris in a tubular structure, such as a tubular structure used in a medical application, particularly one that does not involve moving the debris distally.

FIGURES

These and other features, aspects and advantages of the present invention will become better understood with regard to the following description, appended claims, and accompanying figures which show various views of embodiments of the device, and some of the steps in certain embodiments of the method of the present invention.

DESCRIPTION

According to one embodiment of the present invention, there is provided a device for removing debris from a tubular structure. According to another embodiment of the present invention, there is provided a method for removing debris from a tubular structure. In one embodiment, the method comprises providing a device according to the present invention.

As used in this disclosure, the term "comprise" and variations of the term, such as "comprising" and "comprises," are not intended to exclude other additives, components, integers or steps.

5 As used in this disclosure, the term "tubular structure" should be understood as any elongated structure having a continuously hollow lumen extending from a proximal end to a distal end. The term "tubular structure" encompasses catheters, drains, tubes, and any other similar device.

10 All dimensions specified in this disclosure are by way of example only and are not intended to be limiting. Further, the proportions shown in these Figures are not necessarily to scale. As will be understood by those with skill in the art with reference to this disclosure, the actual dimensions of any device or part of a device disclosed in this disclosure will be determined by its intended use.

15 Although the present invention is disclosed specifically with reference to its applications in the medical field, the invention can also be used in any other suitable application, including other non-medical commercial or industrial applications, as will be understood by those with skill in the art with reference to this disclosure.

20 According to one embodiment of the present invention, there is provided a device for removing debris from a tubular structure. Referring now to Figures 1-4, there are shown lateral perspective views of one embodiment of a device, or portions of the device, for removing debris from a tubular structure according to the present invention. As can be seen, the device comprises a proximal end, a distal end and an intermediate segment between the proximal end and the distal end. The proximal end comprises a handle suitable for interfacing with the hand of an operator. The distal end comprises a radially expandable portion and, most distally, a tip. The radial expandable portion can be a sponge pledget, as shown, or can
25 be any other suitable structure such as a mass of radially expanding fibers, as will be understood by those with skill in the art with reference to this disclosure. The tip is generally made of a firm material, tapering distally and preferably comprises a biocompatible, low

friction material such as Teflon® to reduce friction between the tip and the luminal surface of the tubular structure. The intermediate segment comprises a structure capable of transmitting force from the proximal end to the distal end, and is capable of flexing laterally. In one embodiment, the intermediate segment is a pusher wire.

5 The device further comprises an outer sheath surrounding as least a portion of the intermediate segment. The sheath is also capable of flexing laterally. In one embodiment, the sheath comprises a plastic or wire coil; however, the sheath can comprise any suitable material, as will be understood by those with skill in the art with reference to this disclosure. In a preferred embodiment, the sheath comprises a substantially non-flexible proximal collar at
10 the proximal end, and a distally flaring distal collar at the distal end, as shown. The proximal collar is configured to prevent the proximal end of the device from entering the central portion of the sheath. The distal collar is configured to permit the radially expandable portion of the distal end of the device to be retracted into the sheath, as shown specifically in Figure 2 and Figure 3.

15 In a preferred embodiment, the device further comprises a bag extending proximally from the proximal collar of the sheath to a fitting distally. The bag is capable of being compressed axially and of telescoping axially. The bag is configured to protect the portions of the device inside the bag as the device is introduced into the tubular structure. The fitting is configured to interface with the proximal end of the tubular structure into which the device is
20 being introduced. In one embodiment, the fitting is a "Christmas Tree" type fitting as shown in Figure 4. Any other type of fitting, however, can be used that is suitable for the specific type of tubular structure being cleaned, as will be understood by those with skill in the art with reference to this disclosure. For example, the fitting can be of a Luer-lock type.

 In another preferred embodiment, the device further comprises a removable tab
25 surrounding the intermediate segment, immediately distal to the proximal end of the device, as shown in Figure 4. The tab prevents extrusion of the distal end of the device from the distal collar of the sheath. The tab comprises an easily tearable material, such as paper, or is

perforated along a line parallel to the long axis of the intermediate segment, so that the tab can be separated from the intermediate segment, thereby permitting the distal end of the device to extrude through the distal collar of the sheath.

5 In a preferred embodiment, the device further comprises a removable protective cover over the distal end and, if present, over the fitting.

The device, and its various parts, comprises any material suitable for the purposes disclosed in this disclosure. When used in medical applications, the device will generally comprise one or more than one biocompatible material. In one embodiment, the device comprises one or more than one material that can be sterilized. In another embodiment, the
10 device comprises one or more than one material that can be discarded without creating a significant biohazard.

The device, and its various parts, are manufactured according to techniques well known to those with skill in the art, as will be understood by those with skill in the art with reference to this disclosure.

15 According to another embodiment of the present invention, there is provided a method for removing debris from a tubular structure. The steps shown are not intended to be limiting nor are they intended to indicate that each step depicted is essential to the method, but instead are exemplary steps only. In one embodiment, the method comprises providing a device according to the present invention.

20 Referring now to Figure 5 through Figure 8, and referring back to Figure 1 through Figure 4, there are shown some of the steps in certain embodiments of the method of the present invention. As can be seen, the method comprises, first, providing a device for cleaning a tubular structure. In a preferred embodiment, the device provided is a device according to the present invention. Then, the cover at the distal end of the device is removed,
25 if present.

Next, the fitting is inserted into the proximal end of the tubular structure to be cleaned, creating a seal between the fitting and the proximal end of the tubular structure. Then, an

operator transmits axial force in a distal direction to the proximal end of the device and, thereby, through the intermediate segment, causing the distal end of the device to advance distally through the tubular structure, until the distal end of the device passes distal of the debris that needs to be cleaned from the tubular structure, as shown most specifically in Figure 5 and Figure 6.

Next, the tab is removed and the operator applies additional force to the proximal end of the device, causing the distal end of the device to extrude from the distal collar of the sheath. Once extruded, the distal end of the device expands radially to substantially fill the tubular structure distal to the debris, as can be seen most clearly in Figure 7. Then, the operator transmits axial force in a proximal direction to the proximal end of the device and, thereby, through the intermediate segment, causing the distal end of the device to retract proximally, moving the debris proximally in the tubular structure. The debris is moved proximally until it is enclosed by the bag. The device is then completely removed from the tubular structure and the tubular structure reattached to any other instruments or machines as required.

Although the present invention has been discussed in considerable detail with reference to certain preferred embodiments, other embodiments are possible. Therefore, the scope of the appended claims should not be limited to the description of preferred embodiments contained in this disclosure. All references cited herein are incorporated by reference to their entirety.

WHAT IS CLAIMED IS:

1. A device for removing debris from a tubular structure as disclosed in this disclosure.

5 2. A method for removing debris from a tubular structure as disclosed in this disclosure.

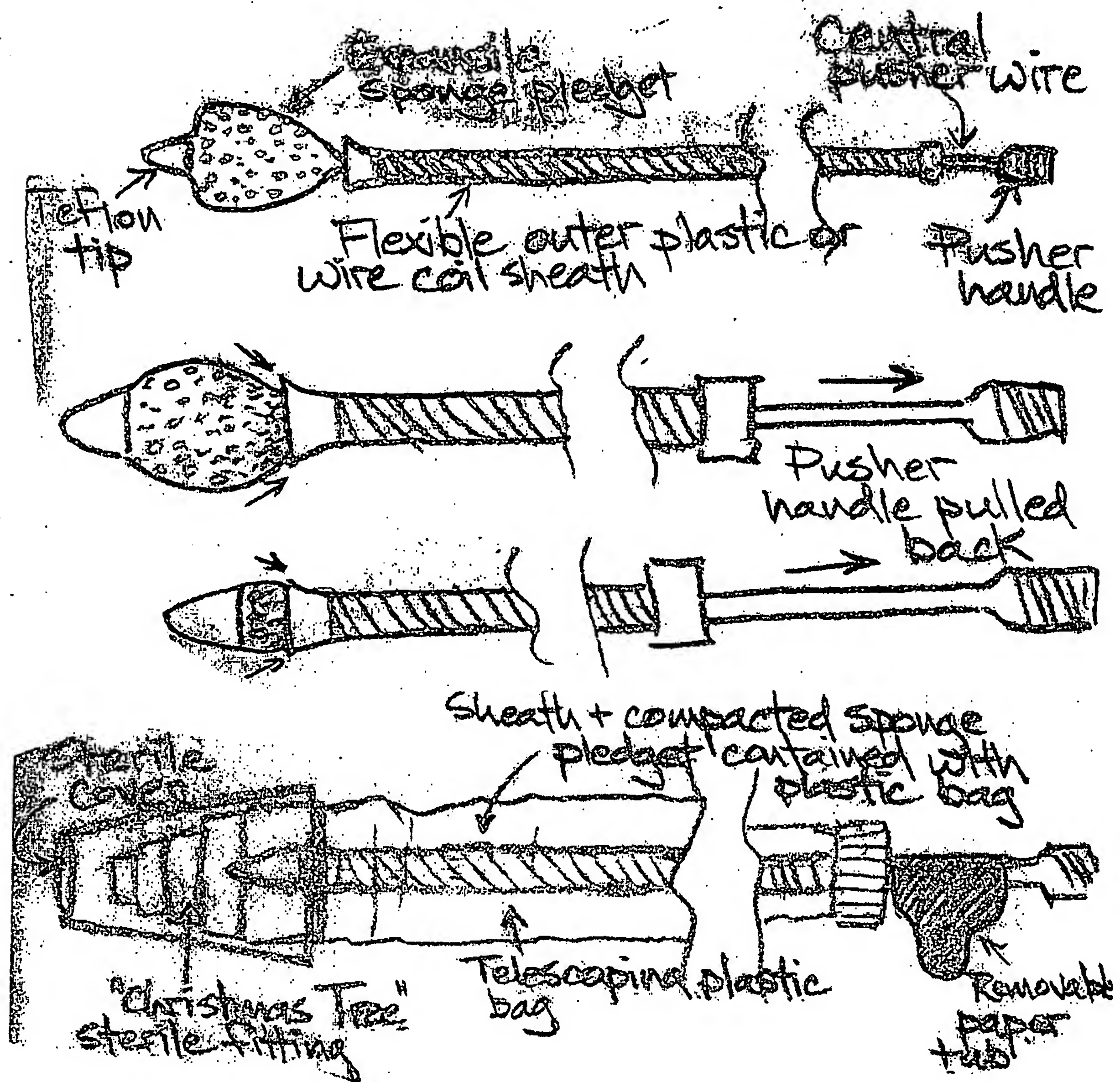
3. The method of claim 2, comprising providing a device according to the claim 1.

PATENT

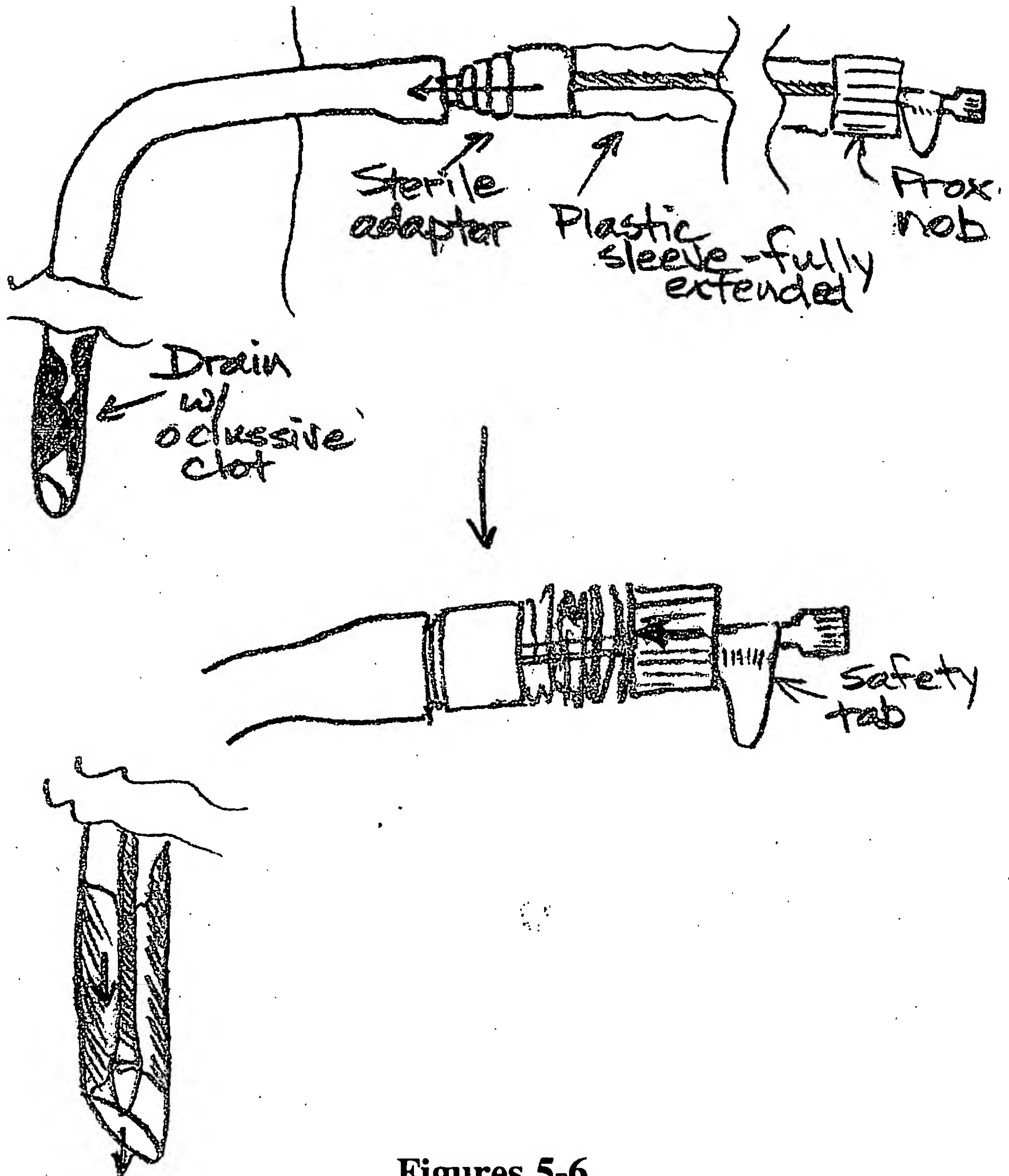
15731

ABSTRACT

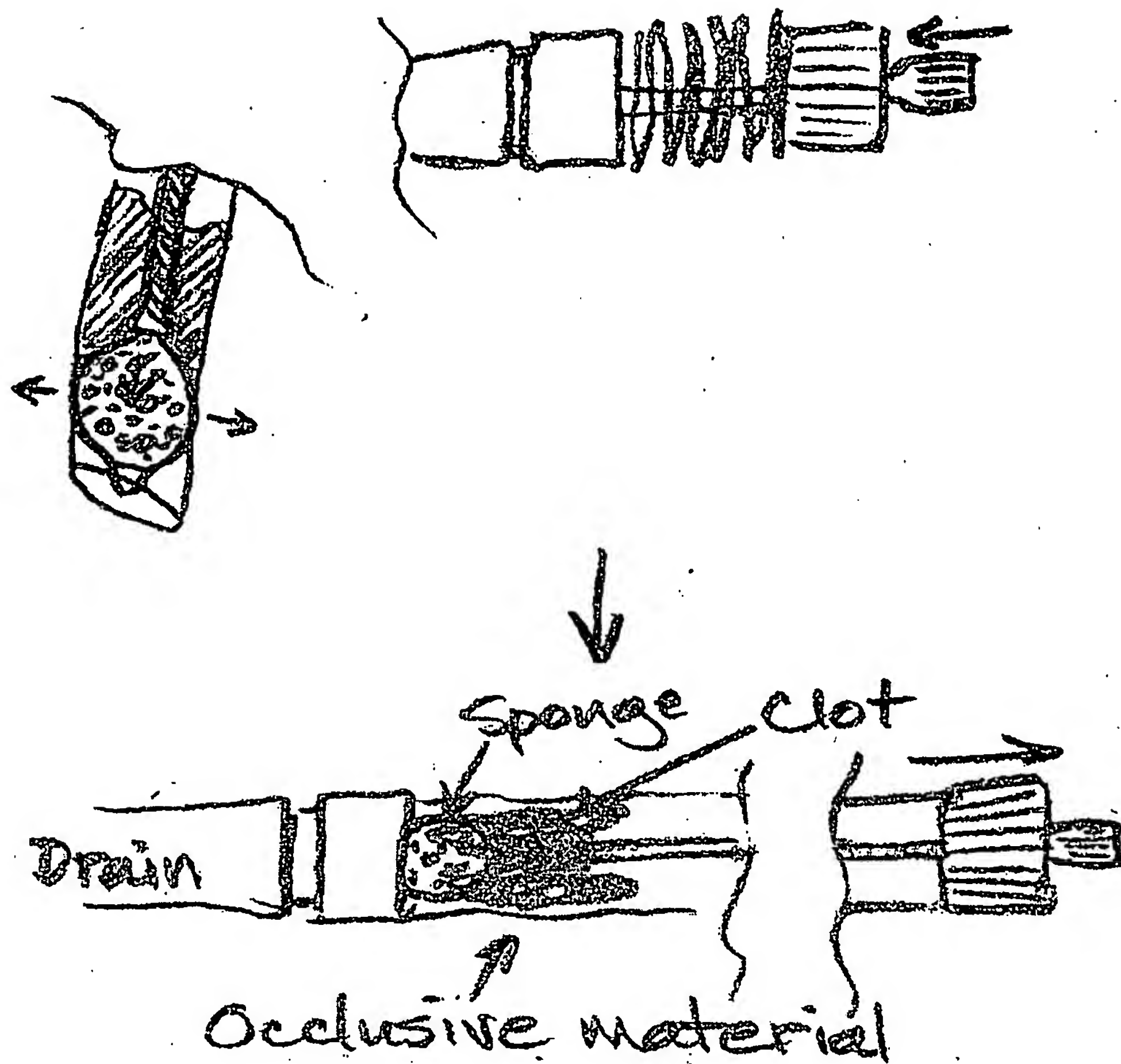
A device for removing debris from a tubular structure. A method for removing debris from a tubular structure. In one embodiment, the method comprises providing a device according to the present invention.



Figures 1-4



Figures 5-6



Figures 7-8

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
6 July 2006 (06.07.2006)

PCT

(10) International Publication Number
WO 2006/071855 A3

(51) International Patent Classification:
A61M 29/00 (2006.01)

(21) International Application Number:
PCT/US2005/047039

(22) International Filing Date:
23 December 2005 (23.12.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/638,597 23 December 2004 (23.12.2004) US
PCT/US2005/000508
7 January 2005 (07.01.2005) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

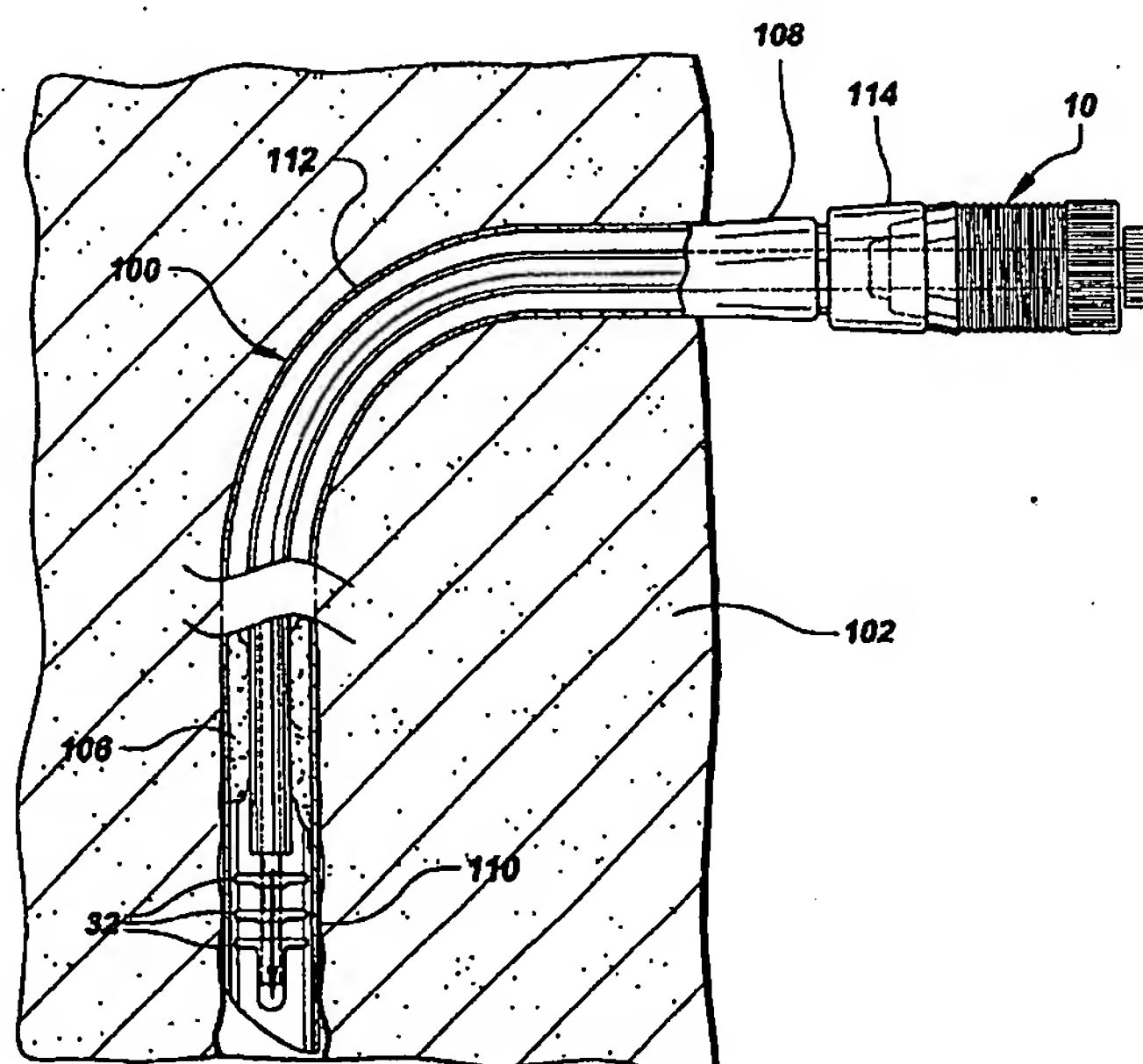
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

[Continued on next page]

(54) Title: METHOD AND DEVICE FOR REMOVING AN OCCLUSION



(57) Abstract: A device for removing an occlusion from within the central lumen of a tubular structure, where the device comprises an occlusion removing structure having a low profile configuration and having a high profile configuration. A method for removing an occlusion from within the central lumen of a tubular structure, where the method comprises providing a device according to the present invention.

WO 2006/071855 A3



— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(88) Date of publication of the international search report:
17 August 2006

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/47039

A. CLASSIFICATION OF SUBJECT MATTER

IPC: A61M 29/00(2006.01)

USPC: 604/104

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/104, 264, 523, 96.01

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5573517A (Bonutti et al.) 12 November 1996 (12.11.1996), see entire patent.	1-40

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

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Date of the actual completion of the international search

12 June 2006 (12.06.2006)

Date of mailing of the international search report

29 JUN 2006

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